REMARKS

Amendment summary

Claims 57-60 are added. Support for Claim 57 may be found, e.g., in at least Claims 1, 7, 9-11, and 25-26 as originally filed. Support for Claim 58 may be found, e.g., in at least Claims 1, 7, 9-11, and 14-16, and 22 as originally filed. Support for Claims 59-60 may be found, e.g., in at least Claim 28 as originally filed.

No new matter is added by this Amendment, and Applicants respectfully submit that entry of this Amendment is proper.

Claims 1, 7-16, 20-28, 38, and 42-44 are all the claims pending in the application.

Status of the claims

Claims 1, 5-16, 21-28, 38, 43, and 44 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lobb et al. (J. Am. Chem. Soc., 2001) in view of Kataoka et al. (Adv. Drug Delivery Rev., 2001), evidenced by Dalmark et al. (J. Gen. Physiol., 1981) (hereinafter "Lobb," "Kataoka," and "Dalmark," respectively). Claims 20 and 42 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lobb in view of Kataoka and Coessens et al. (Prog. Poly. Sci., 2001) (hereinafter "Coessens"), evidenced by Dalmark.

Claims 57-60

These claims recite the partition coefficient of the active, and Applicants respectfully submit that these claims are not anticipated or rendered obvious by Lobb in view of Kataoka

because doxorubicin does not fall within the scope of the recited partition coefficient. With respect to Claims 59 and 60, these claims refer to a cytotoxic compound, which is not anticipated or rendered obvious by Lobb because Lobb discloses providing biocompatible block copolymers. The reference to the fibrinogen assay in Lobb indicates that the polymers therein are intended to be biocompatible. It would not be obvious to a person having ordinary skill in the art to incorporate a cytotoxic drug into polymers intended to be biocompatible.

Response to rejection of Claims 1, 5-16, 21-28, 38, 43, and 44 under 35 U.S.C. § 103 based on Lobb in view of Kataoka, evidenced by Dalmark

Claims 1, 5-16, 21-28, 38, 43, and 44 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lobb in view of Kataoka, evidenced by Dalmark. Applicants respectfully traverse this rejection because (1) as opposed to the position set forth in the Office Action, Dalmark does not disclose that doxorubicin has a partition coefficient between octanol and water of at least 1.5; (2) that the teachings of Lobb have been misinterpreted; and (3) that it would not be obvious to combine the teachings of Lobb and Kataoka in the manner set forth in the Office Action.

Independent Claim 1 recites an aqueous composition comprising an amphiphilic block copolymer having a hydrophilic block and a hydrophobic block, dispersed in the form of micelles in the composition, and a biologically active compound having a measured and/or calculated partition coefficient between octanol and water of at least 1.5 associated with the copolymer in the core of the micelles. The hydrophilic block is formed by radical polymerisation of ethylenically unsaturated monomers comprising a zwitterionic monomer, whereby the hydrophilic block has pendant zwitterionic groups.

With respect to the presently recited partition coefficient between octanol and water of at least 1.5 (point (1) above), Applicants respectfully submit that the cited references do not disclose or suggest this aspect of the claims. Applicants preliminarily note that the Office Action referred to disclosure in Kataoka of doxorubicin as a hydrophobic drug. However, doxorubicin is not a hydrophobic drug. Dalmark is then cited as evidence that doxorubicin has a partition coefficient between octanol and water of more than 1.5. Applicants respectfully submit that Dalmark does not show data relating to the presently recited partition coefficient. Dalmark instead shows data relevant to a different partition coefficient, namely that between octanol and tris buffer (rather than the presently recited water). The legend to Figure 4a in Dalmark sheds light on this because the legend makes clear that the X-axis in Figure 4a relates not to the concentration of tris buffer, but rather to the concentration of doxorubicin. The actual concentration of tris buffer is not specified. Dalmark is therefore not inconsistent with the present specification, which lists the partition coefficient of doxorubicin in octanol and water as 1.04 (see page 23 of the present specification). Accordingly, there is no disclosure or suggestion in any of the cited references relating to a biologically active compound having a partition coefficient between octanol and water as defined in claim 1, and the cited references thus do not render obvious the presently claimed invention.

Applicant also respectfully submits that the presently claimed invention is not rendered obvious by the cited references because the teachings of Lobb have been misinterpreted (point (2) above). The Office Action indicated that the fibrinogen in Lobb is a biologically active compound associated with the polymer. However while Lobb suggests that the MPC-DEA

diblock copolymer therein could have promise in drug delivery applications, Lobb does not mention any specific drugs. To this end, the reference in Lobb to fibrinogen at page 7914, right hand column, first full paragraph, does not refer to fibrinogen as a drug. Applicant notes that the fibrinogen binding in Lobb is an assay which is carried out to assess the haemocompatibility of materials potentially used in contact with blood. Fibrinogen binding is the first step in the blood clotting cascade. Thus, if fibrinogen binding can be reduced (for instance by providing a coating on a surface) then blood clotting is expected to be reduced. Fibrinogen binding is mentioned in Lobb as being an indicator that coatings of the block copolymer could have useful haemocompatibility.

In Lobb, it is mentioned that the block copolymers, coated onto a PET substrate, gave a 76% reduction in fibrinogen binding. This is suggested to be an indicator of good biocompatibility. Fibrinogen is not being referred to in this passage as a therapeutically active compound, and is certainly not an example of the drug which it is suggested may be delivered by the block copolymers. It should be understood further from Lobb that, when the micellar compositions are used to coat the PET substrate, they do not contain fibrinogen. Instead, fibrinogen contacts the polymer coatings only after the polymer has produced a coating, at which point the water has been removed and the polymer is no longer in the form of micelles. During the fibrinogen binding assay, therefore, at no point is fibrinogen associated with micellar polymer. Accordingly, Applicants respectfully submit that Lobb has been misinterpreted with respect to the present claims.

Applicants also note that the Examiner has correctly not suggested that fibrinogen is a hydrophobic drug, that is a drug having a partition coefficient between octanol and water of at least 1.5. Applicants note that even if fibrinogen were to be considered a biologically active compound of relevance to that term in Claim 1, it does not have a partition coefficient of at least 1.5 - it has a partition coefficient of less than 1.0.

Applicants also respectfully submit that it would not be obvious to combine the teachings of Lobb and Kataoka in the manner set forth in the Office Action (point (3) above). The block copolymers of Kataoka are all based on polyethylene glycol as the hydrophilic block. These block copolymers are different than the block copolymers with which Lobb is concerned, which use MPC polymers as the hydrophilic block. In this regard, Applicants note that claim 1 has been amended to recite that the hydrophilic block to polymers are formed by radical polymerisation of ethylenically unsaturated monomers including zwitterionic groups. Accordingly, the polyethylene glycol disclosed in Kataoka does not lie within the present claims because it is not a polymer formed by radical polymerisation of ethylenically unsaturated monomers.

Further in this respect, Applicants note that there is nothing in Kataoka that would suggest to a person having ordinary skill in the art that its teachings relating to PEG-based block copolymers would be applicable to other types of block copolymers, such as those described within Lobb. Applicants therefore submit that there would be no reason for a person attempting to put Lobb's suggestions of utilizing the block copolymers therein in a drug delivery context, to look to Kataoka for useful teachings.

In view of the above, Applicants respectfully submit that the cited references do not render obvious the presently claimed invention because (1) Dalmark does not disclose that doxorubicin has a partition coefficient between octanol and water of at least 1.5; (2) that the teachings of Lobb have been misinterpreted; and (3) that it would not be obvious to combine the teachings of Lobb and Kataoka in the manner set forth in the Office Action. Applicants therefore respectfully request the reconsideration and withdrawal of this § 103 rejection.

Response to rejection of Claims 20 and 42 under 35 U.S.C. § 103 based on Lobb in view of Kataoka and Coessens, evidenced by Dalmark

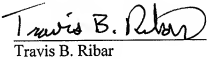
Claims 20 and 42 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lobb in view of Kataoka and Coessens, evidenced by Dalmark. Applicants respectfully submit that the rejection has been rendered moot by the amendment to the claims, and request the reconsideration and withdrawal of this rejection.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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